This Program Announcement expires on October 17, 2003, unless reissued.

NIAMS SMALL GRANT PROGRAM FOR NEW INVESTIGATORS

Release Date: December 5, 2001

PA NUMBER: PAR-02-030

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(http://www.niams.nih.gov)

Application Receipt Dates: February 22, 2002, June 21, 2002,
and October 18, 2002; February 21, 2003,
June 20, 2003, and October 17, 2003.

THIS PA USES "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. MODULAR INSTRUCTIONS MUST BE USED FOR RESEARCH GRANT APPLICATIONS UP TO $250,000 PER YEAR. MODULAR BUDGET INSTRUCTIONS ARE PROVIDED IN SECTION C OF THE PHS 398 (REVISION 5/2001) AVAILABLE AT http://grants.nih.gov/grants/funding/phs398/phs398.html.

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is seeking small grant (R03) applications to stimulate and facilitate the entry of promising new investigators into areas of research of interest to the NIAMS. This solicitation will provide support for pilot research that is likely to lead to a subsequent individual research project grant (R01).

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS led national activity for setting priority areas. This Program Announcement (PA), "NIAMS Small Grant Program for New Investigators," is related to the chronic diseases priority area. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Faith-based organizations are eligible to apply for these grants. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators. Applications are especially encouraged from new investigators who hold a faculty position at an HBCU (Historically Black College or University) or other institutions that have student populations consisting predominantly of individuals from racial or ethnic groups that are underrepresented in science. Foreign organizations and institutions are not eligible. Participation in the program by investigators at minority serving institutions is strongly encouraged. Grants awarded through this PA may not be used to support thesis or dissertation research.

Former and current recipients of Academic Research Enhancement Awards (AREA) (R15), Mentored Clinical Scientist Development Awards (K08), Mentored Research Scientist Development Awards (K01), Mentored Patient-Oriented Research Career Development Award (K23), Shannon Awards (R55), or Individual (F32) or Institutional (T32) National Research Service Award (NRSA) training support are eligible to apply for this Small Grant Program, dependent upon the status of other support for the project. Any current support by the F32 or T32 mechanisms must terminate before Small Grant support begins. Individuals whose sole previous support has been through pilot and feasibility studies (with the exception of R21 support from NIAMS) may apply. Current and previous recipients of NIH funding through Research Project Grants (R01), FIRST (R29) awards or any non-mentored career development award mechanism are ineligible for this Small Grants Program. The NIAMS will not award a new R03 grant if the project period of the new grant would overlap with the project period of a previously awarded NIAMS R03 grant. In addition, the NIAMS will not accept an R03 application from a principal investigator who has held two previous NIAMS R03s. Principal Investigators of research subprojects of Research Program Projects (P01) and Centers (P50 and P60) and individuals who have received research support in arthritis, musculoskeletal, or skin research from the National Science Foundation (NSF) or Department of Veterans Affairs (VA) as Principal Investigators are also ineligible.

Investigators who have questions about eligibility should contact one of the program officials listed under INQUIRIES.

MECHANISM OF SUPPORT

This PA will use the National Institutes of Health (NIH) Small Grant (R03) Award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application submitted in response to this PA may not exceed three years. Applicants may request up to $50,000 (direct costs) per year.

Specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts that have been adopted by the NIH. Complete and detailed instructions and information on Modular Grant applications have been incorporated into the PHS 398 (rev. 5/2001). Additional information on Modular Grants can be found at http://grants.nih.gov/grants/funding/modular/modular.htm.

FUNDS AVAILABLE

It is anticipated that, for FY 2002 and FY 2003, approximately $1.5 million (total costs) will be available for the first year of support for this initiative. It is anticipated that up to 15 to 20 new grants will be awarded each fiscal year under this program. Awards are contingent on the availability of appropriated funds and on the receipt of sufficiently meritorious applications meeting the stated eligibility requirements.

RESEARCH OBJECTIVES

The NIAMS Small Grant program is designed to facilitate the entry of promising new investigators into research on arthritis and musculoskeletal and skin diseases and injuries. Brief summaries of the focuses of the NIAMS' Extramural Program branches are listed below. For more detailed information about scientific areas of interest to the NIAMS, applicants are encouraged to refer to the NIAMS website at http://www.niams.nih.gov.

SUMMARY

o Rheumatic Diseases

The mission of the Rheumatic Diseases Branch is to promote and support research leading to prevention, diagnosis and cure of rheumatic and related diseases. The Branch supports basic, epidemiologic, and clinical research on etiology, pathogenesis, course, interventions, and outcomes in rheumatic and related diseases.

o Muscle Biology

The Muscle Biology Branch encourages and supports research on skeletal muscle, its diseases and disorders, and its central role in human physiology and exercise. Topics include the molecular structure of muscle and the molecular mechanisms that produce force and motion. One focus of this program is understanding the alterations in muscle resulting from increased exercise regimens and, conversely, the atrophy that follows immobilization during injury or illness.

o Musculoskeletal Diseases

This Branch supports studies of the skeleton including bones, joints and associated connective tissues. Broad areas of interest include skeletal development, metabolism, mechanical properties, and responses to injury. Clinical and basic research in the areas of osteoporosis and orthopaedic sciences are of particular interest under this program. Other musculoskeletal disorders of interest include osteoarthritis, osteogenesis imperfecta, and Pagets disease. The Program supports research in the area of acute and chronic injuries of the musculoskeletal system including work-related and repetitive stress injuries. Research proposals related to the development of new technologies with the potential to improve treatment and/or diagnosis of skeletal disorders and to facilitate the repair of trauma in the normal skeleton are of great interest. In addition, bioengineering, sports medicine and musculoskeletal fitness are areas of special research emphasis.

o Skin Diseases

This Branch supports basic and clinical studies of the skin in normal and disease states. The wide range of skin diseases under study with NIAMS support includes keratinizing disorders such as psoriasis and ichthyosis, atopic dermatitis and other chronic inflammatory skin disorders, the vesiculobullous diseases such as epidermolysis bullosa and pemphigus, acne, and vitiligo.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators also may obtain copies of this policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should

not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000, at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html must be used in applying for these grants and will be accepted at the standard application deadlines (http://grants.nih.gov/grants/dates.htm) as indicated in the application kit. This version of the PHS 398 is available in an interactive, searchable format. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

Description of the Research Plan is limited to 10 pages. Information on the new investigator's research background and qualifications should be provided at the beginning of the Research Plan. This information will be used by reviewers in the assessment of the candidate's qualifications to undertake the research proposed in the application.

APPLICATIONS NOT CONFORMING TO THESE GUIDELINES WILL BE CONSIDERED UNRESPONSIVE TO THIS PA AND WILL BE RETURNED WITHOUT FURTHER CONSIDERATION.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and NIH staff. The research grant application form PHS 398 (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html is to be used in applying for these grants, with modular budget instructions provided in Section C of the application instructions.

Applications will request direct costs in $25,000 modules, up to a total direct cost request of $50,000 per year. A typical modular grant application will request the same number of modules in each year.

The title, "NIAMS Small Grant Program for New Investigators," and number of the program announcement (PAR-02-030) must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Dr. Richard Bartlett
Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Blvd., Suite 800 MSC 6500
Bethesda, MD 20892-6500

In order not to delay review, it is important that applicants comply with this request.

Applications received after any of the receipt dates listed above will be deferred to the next review cycle. A Principal Investigator may submit only one R03 application to the NIAMS in any review cycle. Applicants may not submit another research application for the same review cycle in which an R03 is submitted, if that application involves significant scientific overlap with the R03 application.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be evaluated for scientific and technical merit by an appropriate scientific review group convened by NIAMS in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

The goals of NIAMS for this Small Grant program are to attract promising new investigators to conduct research in the rheumatic, musculoskeletal, and skin disease, along with the NIH-wide goals of advancing our understanding of biological systems, improving the control of disease, and enhancing health. The R03 is a mechanism for supporting discrete, well-defined projects that can realistically be expected to be completed within three years and that require only a modest level of funding. Because the research plan is limited to 10 pages, a small grant application will not have the same level of detail or extensive discussion found in an R01 application. Accordingly, reviewers will evaluate the conceptual framework and general approach to the problem, placing less emphasis on methodological details and certain indicators traditionally used in evaluating the

scientific merit of R01 applications (e.g., hypothesis-driven design, supportive preliminary data). In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) Significance. Does this study address an important problem? If the study is descriptive rather than hypothesis-driven, are the importance of the data to be obtained and their potential value in generating future research hypotheses clear? Is the rationale for the study well developed and will the proposed research generate data to answer a specific problem or lead to a larger-scale research project? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the investigator acknowledge potential problem areas and consider alternative tactics? Can the proposed research realistically be accomplished within the requested period of support? Is the proposed approach appropriate to the state of the science, the stage of the research project, and the scope of the work? Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or investigator-generated data. Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. All applications must include a fundamentally sound research plan, but reviewers will consider the applicant's prior research experience in judging the level of detail provided. Preliminary data are not required.

(3) Innovation. Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies, or will the data to be collected provide descriptive information needed to develop a new direction or area of research?

(4) Investigator. Based on the quality of the research and academic record, does he/she show potential to translate previous knowledge, skills, and research experience to areas of interest to NIAMS, and potential to make significant contributions to the field? Is the investigator

appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The reasonableness of the proposed budget and duration in relation to the proposed research

o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o scientific merit (as determined by peer review)
o availability of funds
o programmatic priorities
o candidate's potential as an independent investigator

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

RHEUMATIC DISEASES

Immunology and Inflammation

Dr. Elizabeth Gretz
45 Center Drive, Natcher Bldg. Rm. 5A19J
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
Fax: (301) 480-4543
Email: gretze@mail.nih.gov

Cartilage and Connective Tissue

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Bethesda, MD 20892-6500
Telephone: (301) 594-5032
FAX: (301) 594-4543
Email: TyreeB@mail.nih.gov

Behavioral and Prevention Research

Dr. Deborah Ader
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Bethesda, MD 20892-6500
Telephone: (301) 594-5032
Fax: (301) 480-4543
Email: aderd@mail.nih.gov

Genetics and Clinical Trials

Dr. Susana A. Serrate-Sztein
45 Center Drive, Room 5AS-37G
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
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Email: SzteinS@mail.nih.gov

MUSCLE BIOLOGY

Dr. Richard W. Lymn
45 Center Drive, Room 5AS-49E
Bethesda, MD 20892-6500
Telephone: (301) 594-5128
FAX: (301) 480-4543
Email: LymnR@mail.nih.gov

MUSCULOSKELETAL DISEASES

Osteoarthritis Initiative and Diagnostic Imaging

Dr. Gayle E. Lester
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-43C
Bethesda, MD 20892-6500
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Orthopaedics and Bioengineering

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Bone Biology

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Bone Diseases

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FAX: (301) 480-4543
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SKIN DISEASES

Dr. Alan N. Moshell
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FAX: (301) 480-4543
Email: alan_n_moshell@mail.nih.gov

Direct inquiries regarding review issues to:

Dr. Richard Bartlett
Review Branch, NIAMS
6701 Democracy Blvd., Suite 800 MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-4956
Fax: (301) 402-2406
Email: bartletr@mail.nih.gov

Direct inquiries regarding fiscal matters to:

Melinda Nelson
Grants Management Officer
45 Center Drive, Natcher Bldg. Rm. 5A49F
Bethesda, MD 20892-6500

Telephone: (301) 594-3535
Fax: (301) 480-5450
Email: nelsonm@mail.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846. Awards are made under authorization of sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, and portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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